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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,789	06/23/2006	Philippe Teissier	033339/313045	1481

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1781	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,789	TEISSIER, PHILIPPE	
	Examiner	Art Unit	
	HAMID R. BADR	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *RCE, 7/22/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-12,16-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-12,16-19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/2010 has been entered.

Rejection of claim 8 under 35 U.S.C 112 first paragraph, regarding the deposit of the claimed bacterial strain, is withdrawn per Applicants' representative's statement.

Rejection of claims 2-3, and 21-22 under 35 U.S.C. 112 second paragraph is withdrawn per Applicants' amendment and/or cancellation of claims.

Claims 1, 3-5, 7-12, 16-19 and 21-22 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3-5, 7-12, 16-19 and 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 is indefinite for "wherein said coated particles of lactic acid bacteria are in the form of granules". While coating the lyophilized bacterial preparation is

understood to be the first step, it is not clear whether a granulation process is done after coating the lyophilized bacteria or the coated bacteria are simply called granules.

4. Claim 1 is indefinite for "M_p". It is not clear what is meant by this acronym. If it is meant to denote melting point, it should be spelled out.

5. Claims 11 and 12 are indefinite for "particles of dehydrated bacteria have an average size of between 80 and 150 microns". It is not clear whether the particle size of the coated bacteria or granules are being recited or the bacteria after lyophilization measure 80-150 microns before coating them.

6. Claim 19 is indefinite for "wherein the concentration of coated lactic acid bacteria is ". It is not clear how the coated bacteria can be enumerated per gram of the product.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 3-5, 7-12, 16-19 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shin et al. (US 6,447,823; hereinafter R1) in view of Rutherford et al. (US 5,292,657; hereinafter R2)

9. R1 discloses the incorporation of encapsulated lactic acid bacteria into yogurt wherein the encapsulated lactic acid bacteria are uniformly distributed in the liquid yogurt. (Abstract)

10. R1 discloses that the encapsulation of lactic acid bacteria and their incorporation into yogurt will protect the bacteria so that during the passage of these bacteria through the gastrointestinal tract, the gastric acid will not kill them. (col. 1, lines 50-55)

11. R1 discloses the Lactobacillus, Leuconostoc, Pediococcus, Streptococcus and other lactic acid bacterial including Bifidobacteria bacteria can be encapsulated and incorporated into the yogurt product (col. 4, lines 10-26). Given that R1 discloses the encapsulation and incorporation of lactic acid bacteria into yogurt, it is obvious that such bacteria can include the lactic acid bacteria as presently claimed.

12. R1 also discloses the specific gravity concept and teaches of using encapsulated materials having a specific gravity similar to that of liquid yogurt so that a uniform distribution of particles in the yogurt be achieved. Given that R1 discloses the uniformity of the product based on the specific gravity of the encapsulated material and the liquid yogurt, specific gravities of encapsulated lactic acid bacteria can be manipulated to make them compatible with products containing any concentration of water including the water contents as presently claimed. Depending on the total number of organisms in the encapsulated material, the level at which such encapsulations are incorporated into products can also be manipulated. The amount of encapsulated material is therefore determined by the desired level of microorganisms in the finished product.

13. R1 incorporates the encapsulated bacterial preparation at 0.1 to 1% based on the weight of liquid yogurt. (col. 3, lines 58-60).

14. The liquid yogurt product provides 10^8 cfu/ml of liquid product, and encapsulated lactic acid bacteria will provide 10^6 cfu/ml of the product. (col. 3, lines

61-65). It is noted that the pH of the liquid yogurt will be in the range as presently claimed.

15. While R1 clearly discloses a liquid yogurt containing encapsulated lactic acid bacterial uniformly distributed throughout the liquid product, R1 is generally silent regarding lack of starch in the granules as well as the particle size of the granules in the range as presently claimed.

16. R2 discloses a process for preparing microspheres of freeze-dried microorganisms coated with fatty material.

17. R2 discloses a fatty matrix such as stearic acid having a melting point of 40—75C. (Col. 2 line 62- Col. 3, line3). Given that stearic acid is disclosed by R2, fatty acids as presently claimed, would be obvious.

18. R2 discloses that bacteria such as Lactobacilli, and Bacillus can be used in the process (Col. 3, lines 13-16). R2 is silent regarding the probiotic strains as presently claimed. However, since the probiotic bacteria, including the species claimed, were known in the art at the time the invention was made, their lyophilization and encapsulation/coating according to the methods of R1 and R2 would have been motivated and their incorporation into liquid foods, as disclosed by R1, would have been obvious to an artisan.

19. R2 discloses that the particles (granules) contain 50%-over 90% by weight of the fatty component. (Col. 3, lines 21-23).

20. R2 discloses the particle size range of 75-300 microns with the preferred range being less than 250 microns. (Col. 4, lines 7-9). Granules of less than 200 micron as presently claimed , are then obvious over R1.

21. Given that R2 discloses the use of freeze-dried (lyophilized) bacteria, the use of a lyoprotectant, as commonly practiced in the lyophilization of bacteria, is inherent in the process of freeze-drying disclosed by R2. The particle size of the bacteria and the water activity of the freeze-dried culture are also inherent in the freeze-dried bacterial culture.

22. Given that the matrix is a fatty material containing freeze-dried bacteria, it is clear that the microspheres containing bacteria will be free of starch as presently claimed.

23. Given that a freeze-dried culture is used in the process by R2, the number of dormant organisms in the dehydrated culture will depend on the initial number of those organisms in the culture broth before freeze-drying. It is noted that the total number of the dehydrated organisms in freeze-dried (lyophilized) samples are usually 10^8-10^12 CFU/g, therefore, the bacterial count per gram of the product as presently claimed is obvious.

24. R1 incorporates encapsulated lactic acid bacterial materials into a liquid yogurt in order to protect such bacteria during their passage through the intestinal tract. R2 clearly discloses the preparation of coated (encapsulated) lactic acid bacteria in a matrix which does not contain starch. Additionally the coated bacterial particles have a 75-300 micron size range overlapping the particle size range as presently claimed. Therefore, it would have been obvious to one of ordinary skill in the art to coat (encapsulate) lactic

acid bacteria and incorporate them into liquid foods as taught by R1. However, due to the larger particle size of the encapsulated particles of R1 which can be gritty in mouth, one is motivated to replace those particles with finer particles of R2 which will solve the grittiness problem as well as help the suspension of the particles in the body of the liquid product. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making the coated particles of lactic acid bacterial and use them in liquid foods such as liquid yogurt.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

In light of the new grounds of rejection, some of these arguments are moot.

1. Applicants argue that the liquid food product has at least 90% water and a pH of 4.5 or lower.

a. R1 discloses a liquid food which is a liquid yogurt. Liquid yogurt has a pH lower than 4.5 and at least 90% water. However, since R1 discloses the technique of suspending the encapsulated bacterial preparation comprising adjusting the specific gravity of the particles with that of the liquid food, it would be obvious to adjust the specific gravities for any liquid food and the corresponding encapsulated preparation to prevent the settling out of the suspension. On the other hand, as R2 discloses, encapsulated particles can have particle size as low as 70 microns. Therefore,

employing other techniques, for instance, using emulsifiers will help the stability of such suspension. It is clear that application of such techniques is within the skill of the art.

2. Applicants argue that R2 which discloses the preparation of encapsulated bacterial preparations employs very specific equipment and the method is different from the method used for preparing granules of the present invention.

a. Applicants are reminded that an encapsulated/coated bacterial preparation is being claimed in the instant invention, not a method of preparation of such preparations. Since R2 discloses such a preparation of relevant bacteria, it meets the requirement of claims.

Applicants argument regarding the preparation of the microorganisms of the present invention at ambient temperature is not clear because all the materials used for coating as recited in claim 1 have melting points above 40C.

3. Applicants argue that the teachings of R2 are not relevant for the skilled person in the art; because R2 does not deal with a liquid food.

a. R2 clearly teaches of making encapsulated lactic acid bacteria using coating free of starch and of fatty materials. The range of the particle sized as disclose by R2 overlaps the presently claimed ranges. Therefore, R2 solves the problem with which the present inventors are concerned, thus it is a relevant reference.

4. Applicants argue that the instant invention discloses a liquid food with very good organoleptic quality in that granules are not perceptible in mouth when mixed with a liquid food and therefore there is no feeling of grains of sand on the palate.

a. The grittiness or sandiness of the granules is determined by their particle size range. Since R2 gives a range of granules , 70-300 micron, and specifically states that granules of less than 250 micron are specifically suitable, then it is clear that one of skill in the art shoots for the smallest feasible granules to solve the problem of grittiness or sandy texture. Then it is clear that one would make granules of fine particle size to mitigate the sandiness problem and would certainly be expected to formulate a drink for the delivery of such granules without any sandiness.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr
Examiner
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781